UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,573	11/16/2000	Henryk Taper	TIENSERAFF.2	6030

27667 7590 11/17/2005

HAYES, SOLOWAY P.C.
3450 E. SUNRISE DRIVE, SUITE 140
TUCSON, AZ 85718

EXAMINER	
FAY, ZOHREH A	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/700,573
Filing Date: November 16, 2000
Appellant(s): TAPER ET AL.

Norman P. Soloway
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on August 15, 2005 appealing from the Office action mailed November 1, 2004.

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

The statement of the status of claims contained in the brief is correct.

No amendment after final has been filed.

The summary of claimed subject matter contained in the brief is correct.

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

The copy of the appealed claims contained in the Appendix to the brief is correct.

Evidence Relied Upon:

EP 0692252	Roberfoid	1-1996
6,465,448	Gerson	10-2002
WO 00/61142	Pardee	10-2000

Grounds of rejection:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of certain cancers, does not reasonably provide enablement for "treatment of cancer" in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors to be considered whether a disclosure meets the enablement requirement of 112 first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed.Cir.1988).

The court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation:

1) The quantity of experimentation necessary,

2) The amount of direction or guidance provided,

3) The presence or absence of working examples,

4) The nature of the invention,

5) The state of the prior art,

6) The relative skill of those in the art,

7) The predictability of the art, and

8) The breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in subsection set forth herein below.

1. The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art.

The claimed invention relates to the treatment of cancer, and the art is high, generally that of PHD or MD. This unpredictability has a number of facets as discussed hereinafter.

A. Treatment by cancer type

While the state of the art relatively high with regard to the treatment of specific cancers with specific agents, it has long been underdeveloped with regard to the treatment of cancers broadly. In Particular, there is no known anti-cancer agent, which is effective against all cancers. This is why the National Cancer Institute (NCI) has the extensive in vitro drug screening. As discussed by the court in In re Brana, 51 F. 3d 1560 (Fed. Cir. 1995), in vitro assays are used by NCI (such as the p. 388 and L1210 lymphocytic leukemia tests at issue therein) to measure the potential anti-tumor activity of a candidate compound. Brana at 1562-63. If success is shown in this initial screening step, this demonstrates that at least one cancer type (e.g. lymphocytic leukemia) is sensitive thereto, and provides the incentive to select if for future studies to determine its usefulness as a chemotherapeutic agent against other cancer type.

Thus, a considerable amount of in vitro empirical testing is required with no prior expectation of success being present, before a candidate anticancer agent can be considered useful against any particular cancer type.

B. Combination chemotherapy

Furthermore, the unpredictability observed is compounded when a combination of agents used. This is summarized by WO 00/161142, at page 1, lines 17-23.

Combination therapies while desirable are a hit or miss proposition. The treatments are typically not additive. In many cases, cross effects and treatment load can result in lower effectiveness for the combination, than either treatment alone.

This is verified by the U.S. Patent 6,465,448 at col.1, lines 56-59.

2. The breadth of the claims

The claims are very broad and inclusive of "treatment of cancer" generally.

3. The amount of direction or guidance provided and the presence or absence of working examples.

The specification provides no direction of ascertaining, which cancer will respond to the treatment.

4. The quality of experimentation necessary

The lack of adequate guidance from the specification or prior art with regard to the actual treatment of all cancers in a mammal with the claimed combination fails to rebut the presumption of unpredictability extent in this art. Applicant fails to provide guidance and information required to ascertain which particular type of cancer the claimed anticancer agents will be effective against without restoring to undue experimentation.

Absent a reasonable prior expectation of success using a specific chemotherapeutic agent/combination to treat any type of cancer, one skilled in the art would have to extensively test many various tumor types.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-33 and 35-42 are rejected under 35 U.S.C. 102 (b) as being anticipated by the European Patent Application 0692252. The European Patent Application teaches the use of inulin or oligofructose in combination with an antimetabolite such as methotrexate and fluorouracil for the treatment of cancer. See the abstract and page 3, lines 5-8 and lines 15-16. The above reference makes clear that the claimed components have been previously used in combination.

Appellant's arguments and remarks regarding the 102 (b) rejection have been carefully considered but are not deemed to be persuasive. Appellant in his remarks argues that the prior art does not teach the synergistic combination as claimed herein. The arguments are not well taken. The prior art clearly teaches the use of inulin or oligofructose in combination with the claimed chemotherapeutic agents, such methotrexate and fluorouracil for the treatment of cancer. The word "synergistic" means working together which is taught by the prior art. Appellant's arguments regarding the 112 first paragraph have also been carefully considered, but are not deemed to be persuasive. Appellant in his remarks argues that while the claims are broad they are not overly broad. Appellant also argues that all of the claims specify a particular material inulin and a particular anti-cancer drug, namely an anti-metablic anti-cancer drug. The arguments are not well taken. The 112 first paragraph rejection is directed to the lack of enablement for the treatment of cancer in general, using the combination of

inulin or oligofructose with an anti-metabolic anti-cancer drug. The specification provides no direction for ascertaining, which cancer will respond to the treatment. Furthermore, the unpredictability is compounded when a combination of agents used. It is summarized by WO 00/61142, at page 1, lines 17-23. Appellant's documents filed as exhibits have been carefully reviewed. One document relates to the dictionary definition of "synergism", which indicates acting together. The other documents relate to fluorouracil and methotrexate being used for the treatment of different cancers. Such documents fail to overcome the 112 first paragraph rejection. The lack of adequate guidance from the specification or prior art with regard to the actual treatment of all cancers in a mammal with the claimed combination fails to rebut the presumption of unpredictability in this art. Appellant fails to provide guidance and information required to ascertain which particular type of cancer the claimed combination will be effective against without restoring to undue experimentation.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Z.F

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600

Conferees:

Christopher Low; Michael Hartley

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
Conferee

MICHAEL HARTLEY
PRIMARY EXAMINER